REMARKS/ARGUMENTS

Claims 17-22 were rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

In supporting the rejection, the Examiner states that flavopiridol is the only CDK inhibitor tested. The Examiner also cites the structural diversity of CDK inhibitors as a basis to contend that different CDK inhibitors would behave differently against different biological targets. However, as recognized by the Examiner, and regardless of their structural diversity, they have a common biological property which the present specification teaches is the basis for their usefulness in the present method; CDK inhibition. Applicants assert that it is reasonable to expect other compounds with a similar biological activity to provide results similar to flavopiridol due to their common CDK inhibitor property.

The Examiner also states that there is no evidence that the mixture will be synergistic at any other concentration that the one disclosed in the specification. However, evidence of synergy is not necessary to enable one to treat patients with a combination of the present invention. The case cited by the Examiner relates to an obviousness rejection, not the enablement requirement.

The Examiner further states is that the specification is silent about the correlation between the preclinical experiments described in the Examples and *in vivo* success. However, the present specification clearly teaches that a patient with imatinib-resistant, bcr-abl-positive leukemia would benefit from treatment with a combination of imatinib and a CDK inhibiting compound. It is also clear that the examples are provided to support this conclusion. Therefore, one of ordinary skill would readily surmise that the inventors believed that there was a correlation between the disclosed preclinical experiments and the utility taught.

If a statement of utility contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 USC 112 is satisfied. See, MPEP 2164.01(c). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. However, it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in

a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure. See, MPEP 2164.04.

The Examiner cites Shah et al to support the position that animal data is required to make a reasonable prediction about a drug that is effective *in vitro* for the treatment of bcr-abl imatinib resistant cells. Although this reference discloses both cell line and animal experiments with BMS-354825, it does not support the position that the animal experiments were required before one would reasonably conclude that BMS-354825 would have utility for CML. Applicants request the Examiner to point out the particular portions of this publication that are relied on. Applicants further assert that experiments in cell lines can be predictive.

Gura and Johanson et al are cited to demonstrate general unpredictability in the art of cancer drug discovery. However, such general unpredictability in the art says nothing specifically about the present teachings and provides no reason to doubt the truth of these teachings.

For the reasons discussed above, Applicants request withdrawal of the rejection under the enablement requirement of 35 USC 112, first paragraph.

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,

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